



Substitute for form 1449A/PTO

**Complete if Known**

Application Number	10/633,966
Filing Date	August 4, 2003
First Named Inventor	Ekwuribe, Nnochiri N.
Art Unit	<del>1053</del> 1656
Examiner Name	Hope A. Robinson
Attorney Docket Number	014811-96.22DV

Sheet	1	of	2
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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

Examiner Signature	<i>Dee Robinson</i>	Date Considered	<i>10/28/05</i>
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Substitute for form 1449B/PTO  <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/633,966		
		Filing Date	August 4, 2003		
		First Named Inventor	Ekwuribe, Nnochiri N.		
		Art Unit	4653-1654		
Examiner Name	Hope A. Robinson				
Sheet	2	of	2	Attorney Docket Number	014811-96.22DV

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
HX	B5	KANG CHOON LEE et al.; Isolation, Characterization, and Stability of Positional Isomers of Mono-PEGylated Salmon Calcitonins; Pharmaceutical Research; 1999; Vol. 16, No. 6, pp. 813-818; Plenum Publishing Corporation	
↓	B6	HAESHIN LEE et al.; Preparation and Characterization of Mono-PEGylated Epidermal Growth Factor: Evaluation of <i>in Vitro</i> Biologic Activity; Pharmaceutical Research; 2002; Vol. 19, No. 6, pp. 845-851; Plenum Publishing Corporation	
↓	B7	ANDREA LUCKE et al.; Biodegradable poly(D,L-lactic acid)-poly(ethylene glycol)-monomethyl ether diblock copolymers: structures and surface properties relevant to their use as biomaterials; Biomaterials; 2000; 21, pp. 2361-2370; Elsevier Science Ltd.	
↓	B8	JONG-HOON LEE et al.; Polymeric nanoparticle composed of fatty acids and poly(ethylene glycol) as a drug carrier; International Journal of Pharmaceutics; 2003; 251, pp. 23-32; Elsevier Science B.V.	

Examiner Signature	<i>Hope Robinson</i>	Date Considered	10/28/05
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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FORM PTO-1449 US Dept. of Commerce Patent and Trademark Office		ATTORNEY DOCKET NO. <del>4012-130</del> <b>9233-220V</b>		SERIAL NO. <del>09/439,443</del> <b>to be assigned</b>		
INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)		APPLICANT Nnochiri N. Ekwuribe				
		FILING DATE <b>concurrently herewith</b> <del>December 13, 1999</del>		GROUP Not Yet Assigned		
U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<div style="font-size: 2em;">HAC</div> <div style="font-size: 4em;">↓</div>	AA	5,407,683	18 Apr. 1995	Shively, Merrick L.	424	439
	AB	5,422,364	6 Jun. 1995	Nicolaou, et al.	514	449
	AC	5,439,686	8 Aug. 1995	Desai et al.	424	451
	AD	5,484,809	16 Jan. 1996	Hostetler et al.	514	449
	AE	5,560,933	1 Oct 1996	Soon-Shiong et al.	424	489
	AF	5,608,087	4 Mar. 1997	Nicolaou et al.	549	510
	AG	5,795,909	18 Aug. 1998	Shashoua et al.	514	449
	AH	5,817,840	6 Oct. 1998	Nicolaou et al.	549	510
	AI	5,932,462	2 Aug. 1999	Harris et al.	435	188
FOREIGN PATENT DOCUMENTS						
	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
<div style="font-size: 2em;">HAC</div> <div style="font-size: 4em;">↓</div>	AJ	WO 97/33552	18 Sep. 1997	PCT		
	AK	WO 98/58927	30 Dec. 1998	PCT		
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)						
<div style="font-size: 2em;">HAC</div> <div style="font-size: 4em;">↓</div>	AL	Adams, Jonathan D., et al. "Taxol: A History of Pharmaceutical Development and Current Pharmaceutical Concerns." J. Natl Cancer Inst Monographs (1993) 15: 141-147				
	AM	Arbuck, S.G. "Taxol (paclitaxel): Future directions." Annals of Oncology (1994) 5(Suppl 6): S59-S62				
	AN	Beijnen, Jos H., et al. "Bioanalysis, Pharmacokinetics, and Pharmacodynamics of the Novel Anticancer Drug Paclitaxel (Taxol)." Sem in Oncology (1994) 21 (5) (Suppl 8 October) 53-62				
	AO	Deutsch, H.M., et al. "Synthesis of Congeners and Prodrugs. 3. <sup>1</sup> Water-Soluble Prodrugs of Taxol with Potent Antitumor Activity." J Medicinal Chem (1989) 32: 788-792				
	AP	Greenwald, R.B., et al. "Drug Delivery Systems: Water Soluble Taxol 2'-Poly(ethylene glycol) Ester Prodrugs - Design and <i>in Vivo</i> Effectiveness." J. Medicinal Chem (1996) 39:424-431				
	AQ	Greenwald, R.B. et al. "Highly Water Soluble Taxol Derivatives: 7-Polyethylene Glycol Carbamates and Carbonates." J Org Chem (1995) 60: 331-336				
Continue on page 2						
Examiner <div style="font-size: 1.5em;">Ade Robinson</div>				DATE CONSIDERED <div style="font-size: 1.5em;">10/28/05</div>		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.						

FORM PTO-1449		US Dept. of Commerce Patent and Trademark Office		ATTORNEY DOCKET NO. <del>4012-130</del> 9233-22 DV		SERIAL NO. to be assigned <del>09/459,443</del>	
INFORMATION DISCLOSURE STATEMENT  (use several sheets if necessary)				APPLICANT  Nnochiri N. Ekwuribe			
				FILING DATE Concurrently herewith December 13, 1999		GROUP  Not Yet Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)							
✓	AR	Horwitz, S.B. "TAXOL (paclitaxel): Mechanisms of action." Annals of Oncology (1994) 5 (Suppl.6): S3-S6.					
	AS	Kingston, David G.I. "Taxol: the chemistry and structure-activity relationships of a novel anticancer agent." TIBTECH (June 1994) 12: 222-227					
	AT	Kingston, David G.I. "The chemistry of Taxol." Pharmac Ther (1991) 52: 1-33					
	AU	Kohler, David R., et al. "Paclitaxel (Taxol)." (1994) Pharmacotherapy 14 (1): 3-34					
	AV	Long, Harry J. "Paclitaxel (Taxol): A Novel Anticancer Chemotherapeutic Drug." Mayo Clin Proc (1994) 69: 341-345					
	AW	Parekh, H. et al. "The Transport and Binding of Taxol." Gen Pharmac (1997) 29 (2): 167-172					
	AX	Preston, N.J. "Paclitaxel (Taxol) - a guide to administration." European J of Cancer Care (1996) 5: 147-152					
	AY	Rowinsky, Eric K. et al. "The Clinical Pharmacology and Use of Antimicrotubule Agents in Cancer Chemotherapeutics." Pharmac Ther (1991) 52: 35-84					
	AZ	Rowinsky, Eric K. et al. "Taxol: The First of the Taxanes, an Important New Class of Antitumor Agents." Seminars in Oncology (1992 Dec) 19(6): 646-662					
	BA	Rowinsky, Eric K. et al. "Taxol: Pharmacology, Metabolism and Clinical Implications." Cancer Surveys (1993) 17: 283-304					
	BB	Straubinger, Robert M. et al. "Novel Taxol Formulations: Taxol-Containing Liposomes." J Nat Cancer Inst Monographs (1993) No.15: 69-78					
	BC	Workman, Paul. "Pharmacokinetics and Cancer: Successes, Failures and Future Prospects." Cancer Surveys (1993) 17: 1-26					
✓	BD	Delgado et al. "The Uses and Properties of PEG-Linked Proteins". Critical Review in Therapeutic Drug Carrier Systems, 9(3, 4):249-304 (1992).					
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EXAMINER  Alope Robinson						DATE CONSIDERED 10/28/05	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.							

<b>FORM PTO-1449 U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>  <b>LIST OF DOCUMENTS CITED BY APPLICANT</b>  (Use several sheets if necessary)				<b>Attorney Docket Number</b> 9233-22DV		<b>Serial No.</b> to be assigned  <div style="font-size: 1.5em; font-family: cursive;">10/633,966</div>	
				<b>Applicants:</b> <div style="text-align: right; font-weight: bold;">Ekwuribe</div>			
				<b>Filing Date</b> <div style="font-size: 1.2em; font-family: cursive;">8/4/03</div> concurrently herewith		<b>Group</b> <div style="font-size: 1.2em; font-family: cursive;">1656</div>	
<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
<div style="font-family: cursive;">AK</div>	1.	5,359,030	10/25/94	Ekwuribe	530	303	
	2.	5,438,040	08/01/95	Ekwuribe	514	3	
	3.	5,681,811	10/28/97	Ekwuribe	514	8	
	4.	6,191,105	02/20/01	Ekwuribe et al.	514	3	
	5.	6,309,633	10/31/01	Ekwuribe et al.	424	85.1	
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation Yes   No
<div style="font-family: cursive;">AK</div>	6.	WO97/04796	02/13/97	PCT	—	—	
	7.	WO97/15671	05/01/97	PCT	—	—	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
<div style="font-family: cursive;">AK</div>	8.	Anderson et al., "Structure-Activity Relationship Assessment of Conjugated Enkephalins in Centrally Mediated Analgesia," <i>Soc. Neurosci. Abstr.</i> , 25(1): 180 (1999).					
	9.	Ekwuribe et al., "Oral Insulin Delivery: Hydrolyzable Amphiphilic Oligomer Conjugates Prolong Glucose Reduction," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 26: 147-148 (1999).					
	10.	Freeman et al., "Interactions of Pancreatic Secretory Trypsin Inhibitor in Small Intestinal Juice: Its Hydrolysis and Protection by Intraluminal Factors," <i>Clinica Chimica Acta</i> , 195: 27-40 (1990).					
	11.	Friedman, J. & Halaas, J., "Leptin and the Regulation of Body Weight in Mammals," <i>Nature</i> , 395: 763-770 (1998).					
	12.	Grant et al., "Development of Neuroendocrine Tumors in the Gastrointestinal Tract of Transgenic Mice. Heterogeneity of Hormone Expression," <i>Am. J. Pathol.</i> , 136(6): 1349-1363 (1990).					
	13.	Green, G. & Lyman, R., "Feedback Regulation of Pancreatic Enzyme Secretion as a Mechanism for Trypsin Inhibitor-Induced Hypersecretion in Rats," <i>Proceedings of the Society for Experimental Biology and Medicine</i> , 140(1): 6-12 (1972).					

Hope Robinson

10/28/05

<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office  <b>LIST OF DOCUMENTS CITED BY APPLICANT</b>  (Use several sheets if necessary)		Attorney Docket Number 9233-22DV	Serial No. to be assigned  16/033, 966
		Applicants: Ekwuribe	
		Filing Date 8/4/03 <del>concurrently herewith</del>	Group 1656
14.	Green et al., "Plasma Secretin, CCK, and Pancreatic Secretion in Response to Dietary Fat in the Rat," <i>Am. J. Physiol.</i> , 256: G1016-1021 (1989).		
15.	Gary M. Green, "Feedback Inhibition of Cholecystokinin Secretion by Bile Acids and Pancreatic Proteases," <i>Annals New York Academy of Sciences</i> , 713: 167-179 (1994).		
16.	Herzig et al., "Diazepam Binding Inhibitor is a Potent Cholecystokinin-Releasing Peptide in the Intestine," <i>Proc. Natl. Acad. Sci. USA</i> , 93: 7927-7932 (1996).		
17.	International Search Report corresponding to PCT/US 00/33592; date of mailing: December 12, 2001.		
18.	Jin et al., "Roles of Gut Hormones in Negative-Feedback Regulation of Pancreatic Exocrine Secretion in Humans," <i>Gastroenterology</i> , 107: 1828-1834 (1994).		
19.	Krishnan et al., "Oral Delivery of Calcitonin by Conjugation with Amphiphilic Oligomers," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 26: 149-150 (1999).		
20.	Layer et al., "Feedback Regulation of Human Pancreatic Secretion," <i>Gastroenterology</i> , 98: 1311-1319 (1990).		
21.	Li, Y. & Owyang, C., "Peptone Stimulates CCK-Releasing Peptide Secretion by Activating Intestinal Submucosal Cholinergic Neurons," <i>J. Clin. Invest.</i> , 97(6): 1463-1470 (1996).		
22.	Rodger A. Liddle, "Regulation of Cholecystokinin Gene Expression in Rat Intestine," <i>Annals of the New York Academy of Sciences</i> , 713: 22-31 (1994).		
23.	Rodger A. Liddle, "Cholecystokinin Cells," <i>Annu. Rev. Physiol.</i> , 59: 221-242 (1997).		
24.	Liddle et al., "Luminal Cholecystokinin Releasing Factor (LCRF) Stimulates CCK Release from Intestinal Endocrine Cells Through a Calcium Influx Pathway," <i>Gastroenterology</i> , 116(4): A622 (1999).		
25.	Lu et al., "A Cholecystokinin Releasing Peptide Mediates Feedback Regulation of Pancreatic Secretion," <i>Am. J. Physiol.</i> , 256: G430-435 (1989).		
26.	Mangel et al., "Phenylalanine-Stimulated Secretion of Cholecystokinin is Calcium Dependent," <i>American Journal of Physiology: Gastrointestinal and Liver Physiology</i> , 31(1): G90-G94 (1995).		
27.	Miyasaka, K. & Funakoshi, A., "Luminal Feedback Regulation, Monitor Peptide, CCK-Releasing Peptide, and CCK Receptors," <i>Pancreas</i> , 16(3): 277-283 (1998).		
28.	Miyasaka et al., "Feedback Regulation by Trypsin: Evidence for Intraluminal CCK-Releasing Peptide," <i>Am. J. Physiol.</i> , 257: G175-181 (1989).		
29.	Viktor Mutt, "Secretin and Cholecystokinin," <i>Advances in Metabolic Disorders</i> , 11: 251-320 (1988).		
30.	Parlesak et al., "Parallel Determination of Gut Permeability in Man with M, 400, M, 1500, M, 4000 and M, 10 000 Polyethylene Glycol," <i>Eur. J. Clin. Chem. Clin. Biochem.</i> , 32: 813-820 (1994).		
31.	Prpic et al., "Inhibition of Na <sup>+</sup> /H <sup>+</sup> Exchange Stimulates CCK Secretion in STC-1 Cells," <i>Am. J. Physiol.</i> , 275: G689-695 (1998).		

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		Applicants: Ekwuribe	
		Filing Date 8/4/03 concurrently herewith	Group 1656
ck	32.	Reseland et al., "Inhibitor-Stimulated Non-Parallel Pancreatic Secretion in Man: Hormonal and Neural Regulation?," <i>Scan. J. Gastroenterol.</i> , 30: 72-80 (1994).	
	33.	Reseland et al., "Proteinase Inhibitors Induce Selective Stimulation of Human Trypsin and Chymotrypsin Secretion <sup>1,2</sup> ," <i>J. Nutr.</i> , 126: 634-642 (1996).	
	34.	Saluja et al., "A Cholecystokinin-Releasing Factor Mediates Ethanol-Induced Stimulation of Rat Pancreatic Secretion," <i>J. Clin. Invest.</i> , 99(3): 506-512 (1997).	
	35.	Schwartz et al., "Gastric Branch Vagotomy Blocks Nutrient and Cholecystokinin-Induced Suppression of Gastric Emptying," <i>Am. J. Physiol.</i> , 264: R630-637 (1993).	
	36.	Slaff et al., "Protease-Specific Suppression of Pancreatic Exocrine Secretion," <i>Gastroenterology</i> , 87(1): 44-52 (1984).	
	37.	Spannagel et al., "Purification and Characterization of a Luminal Cholecystokinin-Releasing Factor from Rat Intestinal Secretion," <i>Proc. Natl. Acad. Sci. USA</i> , 93: 4415-4420 (1996).	
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	39.	Spannagel et al., "Bioactivity of Intraduodenally and Intravenously Infused Fragments of Luminal Cholecystokinin Releasing Factor (LCRF)," <i>Regulatory Peptides</i> , 73: 161-164 (1998).	
	40.	Spiegelman B. & Flier, J., "Adipogenesis and Obesity: Rounding Out the Big Picture," <i>Cell</i> , 87: 377-389 (1996).	
	41.	Tarasova et al., "Distribution and Localization of a Novel Cholecystokinin-Releasing Factor in the Rat Gastrointestinal Tract," <i>Endocrinology</i> , 138(12): 5550-5554 (1997).	
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↓	44.	T. A. Wadden, "Treatment of Obesity by Moderate and Severe Caloric Restriction. Results of Clinical Research Trials," <i>Ann. Intern. Med.</i> , 1(119): 688-693 (1993).	

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10/28/05